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### Clinical Results Using the St. Jude Medical "Symmetry" Aortic Connector System in 400 Coronary Artery Bypass Patients

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#### Background:

The St. Jude Medical "Symmetry" aortic-saphenous vein graft connector system was introduced in the U.S. in 2001 as a suture-less method of performing proximal aorto-saphenous vein anastomoses during coronary bypass surgery.

#### Methods:

Over a 27-month period (6/2001 to 9/2003) over 650 aortic-saphenous vein connectors were deployed in 400 coronary artery bypass graft (CABG) patients at our institution. The mean patient age was 66 years (range 37-86), and 65% of patients were male. The majority of patients were first-operation CABG, while 10% (41/400) were either re-do CABG or combined valve-CABG procedures. Off-pump procedures were performed in 28% (99/359) of the first-time CABG procedures. Data for this study were gathered in a prospective fashion with regard to connector usage, while outcomes data were derived retrospectively from the cardiac surgery database.

#### Results:

Only 18 connectors required conversion to a hand-sewn anastomosis after deployment, primarily because of excessive bleeding at the anastomotic site. While re-exploration for bleeding was required in 2.7% (11/400) patients, bleeding was never attributed to the proximal connector site. Neurologic complications (stroke or delirium) occurred in 1.7% (7/400) of patients, and there were no post-operative myocardial infarctions. Post-operative (30-day) mortality was 2.2% (9/400) for this group of patients. To date we have documented only 3 graft failures attributed to the use of the proximal connector, with 2 occlusions and 1 ostial stenosis.

#### Summary:

Our substantial early experience with the "Symmetry" aortic-saphenous vein connector has demonstrated that a precise and hemostatic aortic-proximal saphenous vein connection is created using the system. There has been no documented morbidity related to the use of the connector in over 2 years of use. While long-term results with regard to graft patency have yet to be determined, our short-term operative results using the "Symmetry" connector appear to be no different than historic results for our program.

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### Utility of Routine Functional Testing After Coronary Artery Bypass Graft Surgery: Results From the ROSETTA-CABG Study

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**Background:** There is little consensus regarding the use of functional testing after coronary artery bypass graft surgery (CABG).

**Objectives:** To examine the effects of routine post-CABG functional testing on the use of follow-up cardiac procedures and clinical events.

**Methods:** The Routine versus Selective Exercise Treadmill Testing after Coronary Artery Bypass Graft Surgery (ROSETTA-CABG) Registry is a prospective multicenter study examining the use of functional testing after CABG. A total of 357 patients were enrolled at 16 clinical centers in 6 countries. A functional test was defined as one of the following: exercise treadmill testing, stress echocardiogram or stress nuclear perfusion imaging.

**Results:** During the 12 month follow-up, 95 patients underwent a routine functional testing strategy (100% having functional testing for routine follow-up), while 249 patients underwent a selective strategy (88% having no functional testing and 12% having functional testing for a clinical indication). There was little difference in the rates of follow-up cardiac procedures among the patients undergoing the routine and selective testing strategies (cardiac catheterization 1.1% vs 1.2%, p=NS; percutaneous coronary intervention [PCI] 1.1% vs 0.4%, p=NS; repeat CABG surgery 0.0% vs 0.0%, p=NS). However, clinical events were less common among patients who underwent routine functional testing including unstable angina (0.0% vs 1.6%, p=0.048), death (2.1% vs 0.8%, p=NS), composite clinical events (2.1% vs 2.4%, p=0.03) but not myocardial infarction (0.0% vs 0.0%, p=NS). After controlling for baseline clinical and procedural differences, routine functional testing had a persistent independent association with a reduction in the composite clinical event rate (odds ratio=0.18, 95% confidence interval: 0.04 – 0.85, p=0.03). **Conclusion:** Routine functional testing after CABG is associated with a reduction in the frequency of follow-up clinical events. This association may be attributable to the early identification and treatment of patients at risk for follow-up events, or it may be due to clinical differences between patients who are referred for routine and selective functional testing.

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### Adjunctive Treatment With a Stent-Based Ventricle to Coronary Artery Bypass (VSTENT™) in Patients With Multivessel Disease Undergoing Coronary Artery Bypass Surgery (ADVANTAGE)

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**Background:** We here report on the Munich experience using a stent-based approach for surgical ventricle to coronary artery bypass which provides systolic instead of diastolic blood flow distal to a high grade coronary artery stenosis. In addition to providing flow to the distal vessel, collateral development and arterial remodeling might be induced by VSTENT™ implantation.

**Methods:** In 11 patients (age 60 ± 4 y) undergoing multivessel coronary artery bypass surgery a ventricle to coronary artery bypass was established using a ePTFE-membrane

covered VSTENT™ between the left ventricle and an obtuse marginal branch (n=6), a ramus intermedius (n=1) or a diagonal branch (n=4) distal to a high grade coronary artery stenosis.

**Results:** Epicardial coronary flow (flow wire) measurements including determination of adenosine induced flow reserve and dobutamine stress testing were performed before and after VSTENT™ implantation. Flow wire measurements assessed before and 7 days after VSTENT™ implantation revealed a change of coronary flow pattern from diastolic to predominantly systolic flow (systolic/diastolic flow ratio: 0.3±0.1 to 1.6±0.3, p<0.01). During dobutamine stress testing no regional wall motion abnormalities were detected in the area supplied by the VSTENT™ and none of the patients developed clinical or electrocardiographic signs of ischemia. 6 months angiographic follow up will be available at presentation. **Conclusions:** Surgical VSTENT™ implantation providing a ventricle to coronary artery bypass was feasible and safe in the short term follow up and was associated with a significant change of coronary flow pattern from diastolic to predominantly systolic flow distal to a high grade stenosis of the native vessel at rest and under stress testing.

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### The Introduction of Drug-Eluting Stents Causes a Shift From Coronary Artery Bypass Graft Towards Percutaneous Coronary Intervention: One-Year Outcome of a Single-Center Experience of 2,200 Consecutive Procedures

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**Background:** Sirolimus-eluting stents (SES) were introduced for routine use in Europe in April 2002. To study the impact of this new treatment on the overall clinical management of candidates for revascularization, we evaluated a series of unselected consecutive procedures during 6 months after the introduction of SES and during the 6 months before. **Methods:** Patients who are referred to our institution for coronary revascularization are routinely discussed by a team consisting of thoracic surgeons and interventional cardiologists, who conjointly select the optimal treatment. Since the introduction of SES on April 16, until October 15 2002, 798 consecutive patients were referred to PCI and 275 patients to CABG (SES-group). For comparison, we evaluated a pre-SES group composed of all PCIs (n=806) and CABGs (n=314) performed over the same 6-months period immediately prior to April 15th, 2002. The primary endpoint was major adverse cardiac events (MACE) at one year. **Results:** Compared to the pre-SES era, patients treated with SES had more anatomical complex procedures, such as more multivessel dilations (28% vs 24%; p=0.04), more bifurcation dilations (18% vs 7%; p<0.0001) and the use of more stents (1.9 vs 1.5; p=0.01). In the CABG population a shift was observed towards more 3 vessel disease (3VD: pre-SES:64%, post-SES:77%; p=0.01). At one year PCI patients treated with SES had a 25% reduction in MACE as compared with the pre-SES stent group (14.4% vs 19.6%; p<0.01). Of the CABG patients only 5.0% had MACE in both study phases. **Conclusions:** While the incidence of MACE in CABG patients remained virtually the same, the introduction of SES and the 25% reduction of coronary reinterventions certainly has an impact on clinical practice regarding the choice between CABG or PCI. Despite more multivessel disease patients and the treatment of more bifurcation lesions, the incidence of MACE after PCI decreased. PCI with SES is closing in on CABG.

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### Predictors of 10-Year Patency of Saphenous Vein and Left Internal Mammary Artery Grafts After Coronary Artery Bypass Surgery: Results From a Department of Veterans Affairs Cooperative Study

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**Background:** The long-term success of coronary artery bypass grafting (CABG) is dependent upon the patency of the grafts that are placed at the time of surgery. This VA Cooperative Studies Trial prospectively defined long-term (ten-year) saphenous vein graft (SVG) patency in 1,076 patients and left internal mammary artery (IMA) patency in 471 patients undergoing CABG.

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**Methods:** Patients underwent serial cardiac catheterizations at 1 week, 1 year, 3 years, 6 years and 10 years after CABG.

**Results:** Patency at ten years was 59% for SVGs and 84% for IMA grafts. If a SVG or IMA graft was patent at one week, that graft had a 67% and 87% chance, respectively, of being patent at ten years. At ten years the SVG patency to the LAD (66%) was better (P<0.001) than to the right coronary artery (54%), or circumflex (57%). In vessels > 2.0 mm in diameter the ten-year SVG patency was 88% versus 53% in vessels ≤ 2.0 mm (P<0.001). The other significant positive ten-year predictors of graft patency were age of patient, presence of angina, dyspnea on exertion, vein harvesting technique, serum cholesterol, and use of topical flush to prepare the vein. Type of preservation solution, Canadian Functional Class, cardioplegic solution given via graft, and lowest body temperature are mildly predictive of 10-year graft patency, p=0.05-0.10.

**Conclusions:** Based on prospective angiographic follow-up after CABG, the long-term patency for SVGs is better and the long-term patency for IMA grafts is worse than expected. The best long-term predictors of graft patency are: 1) grafting into the LAD and 2) grafting into a vessel that is >2.0 mm in diameter.

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### Revascularization Alone for Functional Mitral Regurgitation: A Propensity Case-Match Analysis of the Off Pump Coronary Artery Bypass Approach

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**Objective:** Patients with mild or moderate functional mitral regurgitation (MR) are at increased risk for poor outcomes after coronary revascularization. When these patients receive coronary revascularization alone, it is unclear if an off-pump approach (OPCAB) affects outcomes.

**Methods:** 1078 patients with functional mitral regurgitation underwent CABG alone between 1996 and 2002; 222 performed off-pump and 856 using cardiopulmonary bypass (CPB-CABG). Using intraoperative transesophageal echocardiography (TEE), MR was classified as mild (n=848), moderate (n=223), and severe (n=7). Propensity analysis was used to construct matched cohorts of patients with mild and moderate MR undergoing OPCAB(n=127) and CPB-CABG(n=127). Matching variables included age, sex, degree of MR, ejection fraction, number of grafts performed, urgency of operation, previous cardiac surgery, and co-morbidities such as renal disease, diabetes, atherosclerotic aortic disease, peripheral vascular disease, COPD, history of stroke and previous MI.

**Results:** Hospital mortality (6.3% vs. 5.5%, p=0.79) and mid-term(3yr.) survival (90.0% vs. 94.9%, p=0.33) were similar between the CPB-CABG and OPCAB groups, respectively. By multivariable analysis, factors associated with increased hospital mortality were renal disease (Odds Ratio(OR)=8.4, p=0.001), reoperation (OR=5.6, p=0.08), and worse degree of MR (OR=5.2, p=0.01). Mid-term survival was adversely affected by renal disease (OR=4.0, p=0.008), worse degree of MR (OR=2.5, p=0.07, and history of stroke or cerebrovascular disease (OR=2.6, p=0.07).

**Conclusions:** Worsening insufficiency was associated with poorer outcomes in patients with functional MR undergoing coronary revascularization alone, suggesting that they might benefit from mitral valve intervention. Choice of technique (OPCAB vs. CPB-CABG) was not a significant factor in hospital or mid-term mortality.

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### Therapeutic Strategies and Outcomes in Patients With Previous Coronary Artery Bypass Graft Following a New Acute Coronary Syndrome: Insights From the GRACE Experience

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**Background** Prior antecedents of coronary artery bypass graft (CABG) surgery are a clinical feature of risk in patients with an acute coronary event.

**Aim** To compare outcomes in acute coronary syndrome (ACS) patients with a history of CABG who were treated conservatively or invasively.

**Methods and Results** From a total of 30,588 patients included in this prospective analysis of GRACE patients, 3794 had a history of CABG. In-hospital and 6-month follow-up data were available from 3006 and 1638 patients, respectively. During the first 48 h, 405 patients underwent invasive treatment and 2601 conservative treatment. Antiplatelets, antithrombins and glycoprotein (GP) IIb/IIIa inhibitors were more frequently used in the invasive than the conservative group (aspirin 95 vs 89%; thienopyridine 88 vs 23%, LMWH 36 vs 46%, GPIIb/IIIa 70 vs 9%; all P<0.001). Multivariate analysis was performed to adjust for differences in baseline characteristics and potential confounders. Major bleeding and stroke were more frequent in the invasive group. No difference in cardiovascular death was observed between groups at 6-month follow-up. Using the GRACE risk model, an initial conservative approach in patients with prior CABG was not related to a higher risk of in-hospital death/major bleeding.

Table 1: Crude odds ratios using the GRACE risk model (in-hospital events and 6-month follow-up)

| Variables (invasive treatment) | Odds ratio | 95% CI      | P value |
|--------------------------------|------------|-------------|---------|
| <b>Crude</b>                   |            |             |         |
| Major bleeding                 | 1.689      | 1.009-2.829 | 0.046   |
| In-hospital death              | 1.036      | 0.614-1.748 | 0.895   |
| Ischemic event                 | 0.993      | 0.787-1.253 | 0.951   |
| Six-month follow-up            | 0.865      | 0.646-1.159 | 0.332   |
| <b>Adjusted</b>                |            |             |         |
| Ischemic symptoms              | 1.026      | 0.801-1.312 | 0.841   |
| In-hospital death              | 1.166      | 0.609-2.231 | 0.643   |
| Combined endpoints             | 1.057      | 0.835-1.339 | 0.644   |
| Major bleeding                 | 1.499      | 0.828-2.714 | 0.181   |
| Six-month follow-up            | 1.002      | 0.732-1.371 | 0.992   |

**Conclusion** In spite of the imbalance in characteristics, we found no clear beneficial trend in favor of an invasive approach and an increase in the risk of major bleeding or stroke with this approach.

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### Correlation Between Norepinephrine and Epinephrine Myocardial Spillover and Tumor Necrosis Factor-Alpha in Conventional Versus Off-Pump Coronary Artery Bypass Surgery

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**Background:** Complete revascularization obtained by coronary artery bypass surgery does not prevent long term left ventricular remodeling and heart failure development. Periprocedural events linked to different surgical techniques, such as cardiopulmonary bypass with cardioplegic arrest (CABG) versus off-pump procedures may trigger an irreversible microvascular dysfunction or myocytes necrosis and apoptosis.

**Methods:** To test this hypothesis we measured norepinephrine and epinephrine coronary sinus and aortic spillover before and after surgery, simultaneously with Tumor Necrosis Factor-alpha (TNF-alpha) measurements in 30 patients randomized to CABG (n=15), or off-pump (n=15) coronary surgery. Plasma catecholamines were assessed by high performance liquid chromatography and TNF-alpha by ELISA.

**Results:** Norepinephrine and epinephrine spillover was similar in the two groups before surgery, being  $1.38 \pm 0.62$  and  $1.08 \pm 0.45$ , respectively. After surgery norepinephrine spillover was  $1.43 \pm 0.56$ ,  $0.72 \pm 0.49$  in CABG and off-pump, respectively (P<0.05 CABG versus off-pump, means  $\pm$ SD). Epinephrine spillover was  $1.27 \pm 0.16$  and  $0.65 \pm 0.15$  respectively (P<0.05, CABG versus off-pump). TNF-alpha significantly increased only in CABG patients being  $22.17 \pm 6.79$  and  $35.4 \pm 5.98$ , pg/mL, before and after surgery (P<0.05), respectively. After surgery norepinephrine spillover correlated with TNF-alpha levels (P=0.01, R=0.553).

**Conclusions:** Patients undergoing off-pump interventions showed significantly lower catecholamines spillover as compared to CABG, suggesting that the off-pump technique may result less invasive, not only for a lower local and whole body inflammatory response but also for a lower sympathetic drive. For the first time in humans we have detected an increase in epinephrine-spillover after cardiac surgery. Further studies are necessary to evaluate if the short-term advantages observed after off-pump coronary surgery translate into a long-term attenuation of left ventricular remodeling and in the prevention of heart failure progression.

## ORAL CONTRIBUTIONS

815FO

### Featured Oral Session...Unstable Ischemic Syndromes: Intermediate- and Long-Term Outcomes

Monday, March 08, 2004, 2:00 p.m.-3:30 p.m.

Morial Convention Center, Hall A

2:15 p.m.

815-2

### Long-Term Outcome of Patients With Cardiogenic Shock Complicating Acute Myocardial Infarction

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**INTRODUCTION:** Although the early outcome of cardiogenic shock (CS) complicating acute myocardial infarction (MI) has been well documented, the longer term outcome is less well understood.

**METHODS:** The GUSTO I study enrolled patients with AMI from 1989 to 1993 and included 1891 United States patients with CS. Vital status 9 years after study entry is available in 1797 of whom 859 (47%) survived the first 30 days. These 859 patients form the basis of this report.

**RESULTS:** Nine years after study entry, 53% of patients remained alive. Table 1 compares the baseline characteristics of 30-day survivors who did and did not survive 9 years.

| N                     | Alive<br>457   | Dead<br>402    | P     |
|-----------------------|----------------|----------------|-------|
| Male                  | 66.5%          | 65.7%          | .793  |
| Age (yrs)             | 60.6 +/- 10.56 | 66.5 +/- 11.02 | <.001 |
| Diabetes              | 9.9%           | 20.6%          | <.001 |
| Prior MI              | 10.8%          | 26.8%          | <.001 |
| Anterior MI           | 37.7%          | 50.3%          | <.001 |
| Inferior MI           | 60.1%          | 47.8%          | <.001 |
| Revasc within 30 days | 42.7%          | 28.9%          | <.001 |
| PTCA                  | 21.9%          | 21.1%          | .763  |
| CABG                  | 58.3%          | 46.3%          | <.001 |
| PTCA or CABG          |                |                |       |

Using Cox regression methods for multivariable analysis, the following factors were significantly associated with long-term mortality, age > 55, prior MI, diabetes, current smoker, index revascularization all p <.001.

**CONCLUSIONS:** Although early mortality from cardiogenic shock remains high, those